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MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence No.: MFG/IVD/2021/000071

Date: 29/11/2025
Document ID: COA/TN/210TX

Product Name	**Truenat® MTB-RIF Dx**
Generic Name	**Chip-based Real Time PCR Test for Rifampicin Resistant *Mycobacterium tuberculosis***
Lot No.	**210TX**
Set No.	**NA**
Mfg. Date	**2025-10**
Exp. Date	**2027-09**
Pack Size	**50T**
Storage condition	**2°C to 30°C**

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouch Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data				
Samples	**Ct Values**			**Results**
	Tm		**Control**	
	P2	**P1**		
Positive sample 1	66.88 ± 0.31	66.67 ± 0.16	69.41 ± 0.27	RIF Resistance detected
Positive sample 2	72.46 ± 0.29	66.51 ± 0.28	69.79 ± 0.19	RIF Resistance not detected
Positive sample 3	72.62 ± 0.32	66.87 ± 0.22	69.65 ± 0.37	RIF Resistance not detected
Tm- Melting temperature, Ct- Cycle threshold				

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC standards and is approved.

MOLBIO DIAGNOSTICS LIMITED COA

Name : Dr. Praveen Kumar
Department: Quality Control
Designation: QC Head

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